

REMARKS

Claims 1-24 are pending in the application. Claims 7 and 8 have been cancelled from the application. Therefore, claims 1-6 and 9-24 are at issue.

Claim 1 has been amended to incorporate the features of originally filed claims 7 and 8. Support for this amendment can be found in originally filed claims 7 and 8, and in the specification at page 6, lines 10-13, and page 16, line 29 through page 17, line 6, which provides a definition of "free, or essentially free" of a surfactant as recited in claim 8. Claim 16 has been amended to delete a redundant phrase from the claim.

Claims 8 and 16 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite because of the phrase "essentially free" referring to a surfactant component. As stated above, this phrase has been clarified by incorporating the definition of "essentially free" from the specification into claim 1. Claim 8 has been cancelled, and the phrase has been deleted from claim 16. Therefore, in view of the amendments to the claims, it is submitted that the present claims fully comply with 35 U.S.C. §112, second paragraph, and that the rejection should be withdrawn.

Claims 11-24 stand rejected under 35 U.S.C. §102(b) as being anticipated by, or alternatively under 35 U.S.C. §103 as being obvious over, Beerse et al. U.S. Patent No. 6,294,186 ('186). The examiner contends that the '186 patent discloses a claimed composition or renders the claimed compositions obvious. In view of the amendments to the claims, and for the rea-

sons set forth below, it is submitted that this rejection should be withdrawn.

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog and a metal salt ('186 patent abstract). Also see '186 patent, column 3, lines 32-48. The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

"Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent.

The '186 patent discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. See '186 patent, column 47, lines 18-54. The '186 patent contains one example (Example 21) that is free of a metal salt. The composition of this example also contains a total of 10 wt% of surfactants. The definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein

an aromatic carboxylic acid is the sole antimicrobial agent in the composition and the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant. The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention. In contrast to the '186 patent, the present claims exclude the presence of a metal salt that is taught as essential in the '186 patent.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. The major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Example 21 of the '186 patent also is free of a hydric solvent, which is a presently claimed ingredient in an amount of about 5% to about 50%, by weight, of the composition.

It is submitted that the present claims cannot be anticipated by the '186 patent because a difference exists between the '186 patent disclosure and the present claims. The '186 patent fails to teach a composition that contains only an aromatic carboxylic acid as the antimicrobial agent and that contains 0% to 0.2%, by weight, of a surfactant and that contains about 5% to about 50%, by weight, of a hydric solvent. Therefore, the rejection of the present claims as being anticipated by the '186 patent under 35 U.S.C. §102(b) should be withdrawn.

It is further submitted that the differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. The '186 patent stresses the importance of including a metal salt in the composition in order to achieve an enhanced antimicrobial action. The '186 patent also includes 42 examples, of which 41 contain a metal salt as an antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant and is lacking a hydric solvent. The '186 patent fails to teach or suggest a composition that omits a metal salt, and is essentially free of a surfactant, and includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not be motivated to omit a metal salt and omit a surfactant and include a hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be withdrawn.

Claims 1-24 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-26 of U.S. Patent No. 6,451,748 ('748) and claims 1-15 of U.S. Patent No. 6,861,397 ('397). Applicants respectfully submit that the claims

of the present application, as amended, are patentably distinct over claims 1-26 of the '748 patent and claims 1-15 of the '397 patent. Further, applicants submit that in determining obviousness-type double patenting, the questions to be considered is stated in *In re Vogel and Vogel*, 164 U.S.P.Q. 619, 622 (CCPA, 1970), i.e., "Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent?". The CCPA goes on to indicate that, "In considering the question, the patent disclosure may not be used as prior art."

The present claims are directed to an antimicrobial composition and methods of using the composition, comprising an *aromatic carboxylic acid* as the sole antimicrobial agent, a hydric solvent, and a pH-adjusting agent, wherein the composition contains 0% to about 0.2%, by weight, of a surfactant. As amended, all claims recite a composition wherein the aromatic carboxylic acid is the sole antimicrobial agent and is essentially free of a surfactant.

In comparison, issued claims 1-26 of the '748 patent are directed to a composition containing a *phenolic* antimicrobial agent and about 0.1% to about 15%, by weight, of a surfactant. The '748 patent also is directed to composition having a pH of about 6 to about 8, whereas the presently claimed composition has a pH of about 2 to about 5.5.

With respect to issued claims 1-15 of the '397 patent, these claims are directed to compositions containing a topically active compound that is *different from* an antimicrobial compound, as set forth in the recited list of topically active compounds in claim 1.

The '397 patent claims also recite the presence of about 0.1% to about 15%, by weight, of an anionic surfactant and 0% to about 5%, by weight, of a cosurfactant.

Neither claims 1-26 of the '748 patent nor claims 1-15 of the '397 patent teach or suggest using an *aromatic carboxylic acid* as an antimicrobial agent, and let alone as the *sole* antimicrobial agent. In fact, the claims of the '397 patent are *silent* with respect to an antimicrobial agent. The claims of the '748 and '397 patent claims also require a surfactant in amounts up to about 15%, by weight, and the '748 patent claims clearly recites a pH range above the presently recited pH range.

In applying the test set out in *In re Vogel*, applicants submit that the pending claims clearly are not made obvious to one of ordinary skill in the art by claims 1-26 of the '748 patent or claims 1-15 of the '397 patent, directed to a composition either free of an antimicrobial agent or reciting a different antimicrobial agent in a different pH range, and further claiming a high amount of surfactant in the composition.

Furthermore, applicants clearly are not attempting to claim related subject matter in order to extend the patent term of the claims in the '748 or '397 patent which the doctrine of obviousness-type double patenting is intended to prevent. See, e.g., *In re Kaplan*, 229 U.S.P.Q. 278 (Fed. Cir. 1986). Accordingly, it is submitted that the rejection of the pending claims under obviousness-type double patenting over

claims 1-26 of the '748 patent and claims 1-15 of the '397 patent should be withdrawn.

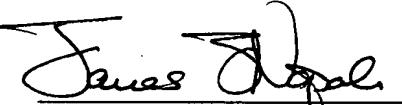
It is submitted that the claims are now of proper form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

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